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| APPLICATION NO.                                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/000,428                                            | 11/30/2001  | Ben-Zion Dolitzky    | 1662/54903          | 9207             |
| 26646                                                 | 7590        | 04/07/2004           | EXAMINER            |                  |
| KENYON & KENYON<br>ONE BROADWAY<br>NEW YORK, NY 10004 |             |                      | BARTS, SAMUEL A     |                  |
|                                                       |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                       |             |                      | 1621                |                  |
| DATE MAILED: 04/07/2004                               |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                        |  |
|------------------------------|--------------------------------------|----------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/000,428 | <b>Applicant(s)</b><br>DOLITZKY ET AL. |  |
|                              | <b>Examiner</b><br>Samuel A Barts    | <b>Art Unit</b><br>1621                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/21/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: On page 1 the specification refers to an US application but fails to give the application numbers.

Appropriate correction is required.

### *Election/Restrictions*

2. Applicant's election with traverse of claims 1-5 and 17-21 in the Paper filed 12/3/2003 is acknowledged. The traversal is on the ground(s) that additional searching would not be an undue burden to the examiner. This is not found persuasive because art anticipating and/or rendering obvious a compound would not necessarily anticipate and/or render obvious a process for making that compound. Thus the examiner would have to continue searching and this would be an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al (WO 00/32555).

The claimed invention is drawn to white crystals of venlafaxine and venlafaxine in a purity of greater than 97%. The prior art generally teaches that venlafaxine is a well-known compound useful for treating depression. Applicants acknowledge that the compound is known to be useful for treating depression. See page 1, last paragraph of the specification.

Jerussi et al on page 23 disclose venlafaxine. The purity appears to be less than what is presently claimed and the color is not white. Therefore, the prior art differs by not teaching the same purity of the claimed compound.

However, this difference is not patentable. It would have been obvious to one having ordinary skill in the art at the time application was made to have used well-known techniques of purification, in order to make a very pure composition of venlafaxine. One skilled in the art would be motivated to make a very pure composition of venlafaxine to eliminate the possibility of side effects that might be associated with the impurities. Furthermore, it has been well established that the mere purity of compound, in itself, does not render a substance unobvious Ex parte Gray (BPAI 1989) 10 PQ2D 1922.

Please note that claims 17-21 are product-by-process claims. Product-by-process claims are limited to the product. See MPEP 2113<sup>1</sup>.

### *Double Patenting*

5. Claim 4 of this application conflicts with claim 2 of Application No.

10/045,510. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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<sup>1</sup> PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


7. Claims 1-3, 5 and 17-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/045,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the degree of purity. Both set of claims are drawn to white crystals of venlafaxine with certain purity. Note that claim 4 of the instant application is identical to claim 2 of the copending application. The other claims have different degrees of purity. However, the change of purity of a pharmaceutical drug is patentably obvious. See reasons recited in the above rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Samuel A Barts  
Primary Examiner  
Art Unit 1621

s.b.